ASSEMBLY BILL No. 1371

Introduced by Assembly Member Yee

February 21, 2003

An act to amend Sections 24173, 24176, and 24178 of the Health and Safety Code, relating to medical research.

LEGISLATIVE COUNSEL'S DIGEST

AB 1371, as introduced, Yee. Human experimentation.

Existing law prohibits any person from being subjected to any medical experiment, as defined, until the person, or in some cases, the legal guardian, conservator, or other representative, has given fully informed consent. Existing law requires, with certain exceptions, any person conducting any medical experiment to make specified disclosures in writing to any human subject or, in some cases, specified other persons, prior to using the human subject in the experiment.

This bill would add the financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment to the disclosures required to be made under this provision.

Existing law makes any person who is primarily responsible for the conduct of a medical experiment and who negligently allows the experiment to be conducted without a subject's informed consent liable to the subject and specifies a minimum and maximum amount of liability. Existing law makes such a person who willfully fails to obtain the subject's informed consent liable to the subject and specifies a maximum amount of liability.

This bill would increase the minimum and maximum amounts of liability in the former provision, and in the latter provision, would

increase the maximum amount and establish a minimum amount of liability.

Existing law makes any person who is primarily responsible for the conduct of a medical experiment and who willfully fails to obtain the subject's informed consent and any representative or employee of a pharmaceutical company who is directly responsible for contracting with another person for the conduct of a medical experiment who willfully withholds certain information, thereby exposing the subject to a known substantial risk of serious injury, guilty of a misdemeanor, punishable by imprisonment in a county jail, a specified maximum fine, or both.

This bill would increase the amount of the maximum fines under these provisions.

Existing law authorizes certain persons to give surrogate informed consent for a person to be subjected to a medical experiment when conducted within an institution that holds an assurance with the United States Department of Health and Human Services in accordance with specified regulations, if that person is unable to give that consent. This authority applies only to medical experiments that relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants.

This bill would extend this authority to give surrogate informed consent, with certain exceptions, to medical experiments that are related to maintaining or improving the health condition of the research participant or obtaining information about the pathological condition of the participant.

The bill would revise the authority of a surrogate decisionmaker under these provisions, would require the person's primary physician to determine the person's capacity to consent to medical experiments, and would allow certain persons to petition the court to determine if the decision or proposed decision of the surrogate decisionmaker is consistent with the person's desires or best interests, as prescribed.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 24173 of the Health and Safety Code is amended to read:

24173. As used in this chapter, ''informed consent'' means the authorization given pursuant to Section 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

(a) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by Section 24172, and ~~such~~ *the* copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.

(b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.

(c) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:

(1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of ~~such~~ *the* procedures, drugs, or ~~device~~ *devices*. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of ~~such~~ *the* experiment shall be informed of ~~such~~ *that* fact~~,~~*;* however, they need not be informed as to whether they will actually be administered or dispensed a placebo.

(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.

(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.

(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(5) An estimate of the expected recovery time of the subject after the experiment.

(6) An offer to answer any inquiries concerning the experiment or the procedures involved.

(7) An instruction to the subject that he or she is free to withdraw his *or her* prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.

(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.

(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.

(10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(11) The financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment.

(d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in Section 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.

SEC. 2. Section 24176 of the Health and Safety Code is amended to read:

24176. (a) Any person who is primarily responsible for conduct of a medical experiment and who negligently allows ~~such~~ *the* experiment to be conducted without a subject's informed consent, as provided in this chapter, shall be liable to ~~such~~ *the* subject in an amount not to exceed ~~one~~ *ten* thousand dollars ~~($1,000)~~ *(10,000)*, as determined by the court. The minimum amount of damages awarded shall be ~~fifty~~ *five hundred* dollars ~~($50)~~ *($500)*.

(b) Any person who is primarily responsible for the conduct of a medical experiment and who willfully fails to obtain the subject's

informed consent, as provided in this chapter, shall be liable to ~~such~~ *the* subject in an amount not to exceed ~~five~~ *twenty-five* thousand dollars ~~($5,000)~~ *($25,000)* as determined by the court. *The minimum amount of damages awarded shall be one thousand dollars ($1,000).*

(c) Any person who is primarily responsible for the conduct of a medical experiment and who willfully fails to obtain the subject's informed consent, as provided in this chapter, and thereby exposes a subject to a known substantial risk of serious injury, either bodily harm or psychological harm, shall be guilty of a misdemeanor punishable by imprisonment in the county jail for a period not to exceed one year or a fine of ~~ten~~ *fifty* thousand dollars ~~($10,000)~~ *($50,000)*, or both.

(d) Any representative or employee of a pharmaceutical company, who is directly responsible for contracting with another person for the conduct of a medical experiment, and who has knowledge of risks or hazards with respect to ~~such~~ *the* experiment, and who willfully withholds information of ~~such~~ *the* risks and hazards from the person contracting for the conduct of the medical experiment, and thereby exposes a subject to substantial risk of serious injury, either bodily harm or psychological harm, shall be guilty of a misdemeanor punishable by imprisonment in the county jail for a period not to exceed one year or a fine of ~~ten~~ *fifty* thousand dollars ~~($10,000)~~ *($50,000)*, or both.

(e) Each and every medical experiment performed in violation of any provision of this chapter is a separate and actionable offense.

(f) Any attempted or purported waiver of the rights guaranteed, or requirements prescribed by this chapter, whether by a subject or by a subject's conservator or guardian, or other representative, as specified in Section 24175, is void.

(g) Nothing in this section shall be construed to limit or expand the right of an injured subject to recover damages under any other applicable law.

SEC. 3. Section 24178 of the Health and Safety Code is amended to read:

24178. (a) Except for this section and the requirements set forth in Sections 24172 and 24176, this chapter shall not apply to any person who is conducting a medical experiment as an investigator within an institution that holds an assurance with the

United States Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations and who obtains informed consent in the method and manner required by those regulations.

(b) Subdivisions ~~(c)~~ *(d)* and ~~(f)~~ *(i)* shall apply only to medical experiments that relate to the cognitive impairment, lack of capacity, or serious or life threatening diseases and conditions of research participants *or that are related to maintaining or improving the health condition of the research participant or related to obtaining information about the pathological condition of the participant*.

(c) *Subdivisions (d) and (i) shall not apply to Phase I clinical studies, as defined by the Center for Drug Evaluation and Research in the United States Food and Drug Administration, or to medical experiments that involve greater than "minimal risk," as defined in Section 50.3(k) of Title 21 of, and Section 46.102(i) of Title 45 of, the Code of Federal Regulations.*

(d) For purposes of obtaining informed consent required for medical experiments in a nonemergency room environment, and pursuant to subdivision (a), if a person is unable to consent and does not *orally* express dissent or *give any other indication of* resistance to participation, surrogate informed consent may be obtained from a surrogate decisionmaker with reasonable knowledge of the subject, who shall include any of the following persons, in the following descending order of priority:

(1) The person's agent pursuant to an advance health care directive *if the person has explicitly authorized the agent to consent to medical experiments in the advance directive*.

(2) The conservator or guardian of the person having the authority to make health care decisions for the person.

(3) The spouse of the person.

(4) An individual as defined in Section 297 of the Family Code.

(5) An adult son or daughter of the person.

(6) A custodial parent of the person.

(7) Any adult brother or sister of the person.

(8) Any adult grandchild of the person.

(9) An available adult relative with the closest degree of kinship to the person.

~~(d)~~

(e) Except as provided in Section 24175, the person's capacity to consent to medical experiments shall be determined by the person's primary physician, as defined in Section 4631 of the Probate Code, and confirmed by a second physician. This determination and confirmation shall be made by someone not otherwise involved in the medical experiment and shall be in writing. If the person's primary physician has a clinical or financial interest in the medical experiment, the person shall be referred to another physician with no clinical or financial interest in the medical experiment for a determination of the person's capacity to consent to medical experiments.

(f) For purposes of subdivision (d), the surrogate decisionmaker shall exercise substituted judgment, making decisions about participation in accordance with the person's individual health care instructions, if any, and other wishes to the extent those wishes are known to the surrogate decisionmaker. Otherwise, the decisionmaker shall make decisions based upon a best estimation of what the person would have chosen if the person was capable of making a decision.

(g) The person's spouse, domestic partner, relatives, or friends, or any other interested person, may petition the court to determine if the decision or proposed decision of the surrogate decisionmaker pursuant to subdivision (d) is consistent with the person's desires as expressed in an advance directive or as otherwise known to the court or, if the person's desires are unknown or unclear, if the acts proposed by the surrogate decisionmaker are in the person's best interest.

(h) (1) When there are two or more available persons who, pursuant to subdivision ~~(c)~~ *(d)*, may give surrogate informed consent and who are in the same order of priority, if any of those persons expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given.

~~(e)~~

(2) When there are two or more available persons who are in different orders of priority pursuant to subdivision ~~(c)~~ *(d)*, refusal to consent by a person who is a higher priority surrogate shall not be superseded by the consent of a person who is a lower priority surrogate.

~~(f)~~

(i) For purposes of obtaining informed consent required for medical experiments in an emergency room environment, and pursuant to subdivision (a), if a person is unable to consent and does not *orally* express dissent or *give any other indication of* resistance to participation, surrogate informed consent may be obtained from a surrogate decisionmaker who is any of the following persons:

(1) The person's agent pursuant to an advance health care directive *if the person has explicitly authorized the agent to consent to medical experiments in the advance directive*.

(2) The conservator or guardian of the person having the authority to make health care decisions for the person.

(3) The spouse of the person.

(4) An individual defined in Section 297 of the Family Code.

(5) An adult son or daughter of the person.

(6) A custodial parent of the person.

(7) Any adult brother or sister of the person.

~~(g)~~

(j) For purposes of subdivision (i), the surrogate decisionmaker shall exercise substituted judgment, making the decision based upon a best estimation of what the person would have chosen if the person was capable of making a decision.

(k) When there are two or more available persons described in subdivision ~~(f)~~ *(i)*, refusal to consent by one person shall not be ~~superceded~~ *superseded* by any other of those persons.

~~(h)~~

(l) A surrogate decisionmaker's authority to consent under subdivisions (d) and (i) shall not supersede the person's right to refuse participation in medical experiments. Participation in the medical experiment shall discontinue if the person orally expresses dissent or gives any other indication of resistance to participation. No behavioral restraint, including manual, mechanical, or chemical restraint, shall be used to secure participation in medical experiments.

(m) Research conducted pursuant to this section shall adhere to federal regulations governing informed consent pursuant to Section 46.116 of Title 45 of the Code of Federal Regulations.

~~(i)~~

(n) Any person who provides surrogate consent pursuant to subdivisions ~~(c)~~ *(d)* and ~~(f)~~ *(i)* may not receive financial compensation for providing the consent.

~~(j)~~

(o) Subdivisions ~~(c)~~ *(d)* and ~~(f)~~ *(i)* do not apply to any of the following persons, except as otherwise provided by law:

(1) Persons who lack the capacity to give informed consent and who are involuntarily committed pursuant to Part 1 (commencing with Section 5000) of Division 5 of the Welfare and Institutions Code.

(2) Persons who lack the capacity to give informed consent and who have been voluntarily admitted or have been admitted upon the request of a conservator pursuant to Chapter 1 (commencing with Section 6000) of Part 1 of Division 6 of the Welfare and Institutions Code.

O